

EXHIBIT 11

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

MASSACHUSETTS INSTITUTE OF
TECHNOLOGY, ET AL.,

Plaintiffs,

v.

DEPARTMENT OF HEALTH & HUMAN
SERVICES,
200 Independence Ave, S.W.
Washington, D.C. 20201

NATIONAL INSTITUTES OF HEALTH,
9000 Rockville Pike
Bethesda, MD 20892

DOROTHY A. FINK, M.D. in her official
capacity as Acting Secretary, Department of
Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

and

MATTHEW J. MEMOLI, M.D., M.S. in his
official capacity as Acting Director, National
Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892,

Defendants.

Case No.

DECLARATION OF ROBERT A. HARRINGTON, M.D.

I, Robert A. Harrington, M.D., declare as follows:

1. I am the Stephen and Suzanne Weiss Dean of Weill Cornell Medicine and Provost for Medical Affairs of Cornell University (“Cornell” or the “University”). I assumed this position on September 12, 2023. I am a cardiologist, past president of the American Heart Association, and

the author of more than 760 peer-reviewed manuscripts, reviews, book chapters, and editorials. I make this declaration in support of the Plaintiffs' Complaint in this matter and the forthcoming Emergency Motion for a Temporary Restraining Order.

2. I have personal knowledge of the contents of this declaration, or have knowledge of the matters based on my review of information and records gathered by Cornell personnel, and could testify thereto.

3. In my role, I am the chief academic officer with oversight of the clinical and educational missions of Weill Cornell Medical College and the Graduate School of Medical Sciences in New York, New York (together, "Weill Cornell Medicine"). Weill Cornell Medicine carries out a wide variety of bench-to-bedside research, including on cancer, cardiovascular disease, metabolic diseases, neurodegenerative diseases, diseases affecting children, and infectious diseases.

4. The federal government has selected Cornell to conduct a wide variety of vital research on behalf of United States citizens, funded in part by agency awards from across the federal government, including but not limited to the Department of Health and Human Services ("HHS") and its National Institutes of Health ("NIH"). For Cornell's fiscal year 2024 (July 1, 2023 to June 30, 2024), Cornell expended approximately \$452 million on 1,693 awards from NIH. On those grants, the University's indirect cost rate was as published and negotiated with the federal government, allowing Cornell to recover \$137 million in reimbursement for those costs from NIH. For Cornell's fiscal year 2025 (July 1, 2024 to June 30, 2025), Cornell holds 1,207 awards from NIH. The NIH awards cover activities across Cornell's different locations, including at its primary campus in Ithaca, New York and Weill Cornell Medicine.

5. Cornell's work in fundamental research on sponsored awards issued by NIH targets important health issues, saves and improves lives, and adds immeasurably to our economy. NIH awards are typically issued for a five-year term, and are often extended for an additional five-year term. Indeed, some NIH sponsored activities continue for decades. Examples of just a handful of the awards that NIH has selected Cornell to perform work on include research on:

- a. Advanced cancer research, including efforts to understand cancer biology, genetics, and epigenetics to develop novel, personalized treatments, especially for aggressive forms of cancer;
- b. Analyzing how immune cells are guided through the body, to aid design of therapies for not only cancer but autoimmune diseases and fibrosis;
- c. The development of new imaging and biomarker strategies to improve early diagnosis and treatment outcomes for neurological conditions and neuroimmune conditions such as chronic fatigue syndrome;
- d. Advanced cardiac imaging and regenerative medicine approaches;
- e. Understanding and addressing fertility challenges in women and men;
- f. Investigations into childhood diseases that aim to reduce infant mortality, improve outcomes for pediatric cancers, enhance treatments for genetic disorders, and optimize pain management in critically ill children;
- g. The development of portable point-of-care diagnostics for nutrition, infection, and cancer; and
- h. Research into regenerative medicine and aging, including analyzing cellular stress responses to find new pathways for treating age-related diseases and improving quality of life in older adults.

6. At Cornell, research funded by the NIH has a direct impact on public health. Funded studies lead to the development of new treatments, cures, diagnostics, and public health interventions. Those studies inform public health policies and improve quality of life for millions of people and also maintain health quality in animals that are integral to the United States food system. In addition, one of the reasons patients seek out Weill Cornell Medicine is because of the presence of physicians at the cutting edge in their fields, in part due to their work on sponsored activities. This allows the patients to receive access to the latest treatments and techniques.

7. On a typical grant, the funding amounts must cover both direct costs (expenses directly related to the specific grant activity) and indirect costs. Indirect costs cover essential expenses such as facilities, utilities, financial administration, and operations that enable research to flourish safely and responsibly, such as research compliance and safety programs, human and animal research protections, and hazardous waste disposal. *See* Office of Management and Budget (“OMB”) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 C.F.R. §§ 200, *et seq.* (the “Uniform Guidance”). Particularly in biomedical research, the specialized laboratory facilities, the need to adhere to specific government regulations for animal welfare and human subject safety in research, and required processes to maintain responsible research mean that these indirect costs are considerable. Historically, the federal government has used a narrower definition of direct costs than is typical in foundation-funded research, mostly to streamline budgeting and minimize administrative burdens on the agencies. Significantly reducing the allowable indirect cost percentage without altering the way in which costs are classified as direct or indirect significantly disrupts the financial model that has supported needed research and innovation across the United States for decades.

8. In addition, as required by the Uniform Guidance, Cornell has negotiated an indirect cost rate with the federal government of up to 64% for its Ithaca campus and 69.5% at Weill Cornell Medicine. The higher negotiated rate for Weill Cornell Medicine reflects the generally higher costs of operating a research enterprise in a large, urban area with an associated higher cost of living.

9. Although the federal government's portion of funds needed for university research has been declining over time, indirect cost reimbursements are vital to the operation of the nation's federal research system, which includes the sponsored activities conducted at Cornell. Direct costs on NIH awards simply fall well short of covering the real, comprehensive cost of sponsored activities including research, and do not reflect the full facilities and administration costs that Cornell must incur in order to be able to perform the work. This is particularly the case for NIH-sponsored activities in biomedical research that include animal welfare and human subjects considerations, and safe use of biological and chemical agents by researchers.

10. As noted above, for Cornell's fiscal year 2024 (July 1, 2023 to June 30, 2024), Cornell expended approximately \$452 million on 1,693 awards from NIH. On those grants, Cornell recovered \$137 million in reimbursement for indirect costs from NIH. Accordingly, the reimbursement of these indirect and vital costs for safe and responsible NIH-sponsored activities represented only 30% of the total cost of those NIH-sponsored activities. Cornell's ability to conduct NIH-sponsored research during its fiscal year 2025 (July 1, 2024 to June 30, 2025) under its 1,207 awards from NIH would be irreparably harmed by an immediate reduction in the committed indirect cost reimbursement by NIH, estimated as a shortfall of over \$42,000,000 over the remainder of this one fiscal year alone.

11. On February 7, 2025, NIH issued Notice NOT-OD-25-068, “Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates” (“NIH Supplemental Guidance”). The NIH Supplemental Guidance provides that effective February 10, 2025, indirect costs allowed on all future awards and going-forward expenses for all existing awards shall be limited to fifteen percent.

12. If NIH’s Supplemental Guidance is permitted to remain in effect, it will irreparably harm research at Cornell that directly benefits public health and American competitiveness. Such a drastic decrease in allowable indirect costs on three days’ notice—especially with regard to currently funded awards on which sponsored research activities are in process and for indirect costs that Cornell has already budgeted for in its current fiscal year—will immediately impair the University’s ability to conduct sponsored research in compliance with the underlying award agreements and applicable laws regarding research safety and human and animal research protocol compliance.

13. For example, without continuing indirect cost reimbursement at Cornell’s negotiated rates, Cornell would no longer be able to carry out all of the sponsored activities and properly maintain the facilities and equipment currently in use. The University does not have sufficient budgeted operational funds to cover a sudden structural decrease in indirect cost recovery for existing awards on an ongoing basis, and would be required to consider layoffs, both for research staff and research administration officers and other employees of the university who perform critical but indirect work in support of sponsored activity (such as custodians, security guards, and so forth), and reductions in administrative costs necessary for research services. This harm is not limited to monetary damages that can be rectified with a compensatory award. For example, even if the indirect cost rate is increased at a later date, if a research facility must be

closed in the interim because its operation and maintenance can no longer be supported, Cornell will immediately lose its investment in that infrastructure and have a diminished ability to undertake that research in the future, even if the NIH Supplemental Guidance were rescinded or invalidated. This change could also impact patients currently enrolled in federally funded clinical trials, who may find their treatment discontinued, leading to potential health risks. Further, Cornell may no longer have the key personnel or materials needed to restart or carry out certain sponsored activities.

14. Cornell necessarily relies on both the direct cost and the indirect cost portions of funding provided with each specific NIH award in formulating its overall operating budget in any given year. Operating budgets rely upon estimates of direct and indirect sponsored funding to plan for annual staffing needs, infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), facility building and renovation, and equipment purchases to support a broad range of overlapping research activities.

15. The harmful impact of the NIH Supplemental Guidance is not limited to Cornell and its employees. For example, the University is by far the largest employer in Tompkins County, New York. If the lower indirect cost reimbursement rate requires layoffs, that loss of employment will be harmful not only to the affected employees and their families, but to the overall economic stability of the County as a whole. The University may have to reduce the quantity of equipment and labor used to maintain its facilities, lowering the economic activity of the County and impairing the funding that flows to essential local government services arising out of that activity.

16. In addition, the NIH Supplemental Guidance will undermine the feasibility of sponsored activity that results in medical and scientific breakthroughs that provide significant social and economic value to the country, sometimes opening up entirely new areas of commercial

development. The United States is a stronger, more secure, and more economically vibrant country as a result of the collective benefits arising from federally sponsored research. Additionally, the next generation of scientists, physicians, engineers, and other skilled workers develop their vitally important expertise while learning and working at research institutions such as Cornell. The NIH Supplemental Guidance would drastically reduce the positive impact of this work and the pipeline of educated professionals that United States industry requires to be internationally competitive. Slowdowns or halts in research by Cornell and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening our nation's national security and its economic dominance.

17. Temporary injunctive relief is vital to protect against these devastating consequences. Even if the NIH Supplemental Guidance is ultimately rescinded or held invalid, Cornell does not have the ability to cover such a radical reduction in indirect cost reimbursement during the course of protracted litigation. Cornell's existing endowment cannot simply be redirected to pick up these losses. The vast majority of endowed funds are restricted by the terms on which the funds were donated to the University and cannot legally be used to cover research infrastructure costs. Moreover, Cornell may only draw down the portion of the endowment that is unrestricted at a rate that complies with New York State law.

18. As a non-profit institution, Cornell reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps. In other words, unlike for-profit organizations, Cornell does not generate significant surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid support for students.

19. Moreover, absorbing the cost of a lower indirect cost rate, even if it were possible, would create long-term budget pressures on Cornell—which would in turn force reductions in key investments supporting Cornell’s faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain Cornell’s academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York
February 9, 2025

A handwritten signature in black ink, reading "R. Harrington MD". The signature is written in a cursive, slightly slanted style.

ROBERT A. HARRINGTON, M.D.